

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0408/042/003

Case No: 2046546

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ranbaxy Ireland Limited

Spafield, Cork Road, Cashel, Co. Tipperary, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Codeine Phosphate Tablets BP 60 mg

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **10/03/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Codeine Phosphate Tablets BP 60 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 60mg codeine phosphate.

Excipient: Also contains 73.1 mg lactose (as monohydrate).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White, circular, biconvex tablet about 7.1 mm in diameter, embossed with 'R117'.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Adults:

As an analgesic in mild to moderate pain, as an anti-tussive, and for the treatment of chronic diarrhoea.

Children:

As an analgesic in mild to moderate pain and for occasional use in the control of intractable diarrhoea under specialist supervision.

4.2 Posology and method of administration

For oral administration.

In mild to moderate pain:

Adults: 30-60mg every four hours when necessary to a maximum of 200mg daily.

Children (6-12 years): 3mg per kilo of bodyweight daily in divided doses.

As an anti-tussive:

Adults: 15-30mg three or four times daily. Not recommended for children.

For the treatment of chronic diarrhoea:

Adults: 15-60mg every four to six hours.

Children over six years: 1-3mg per kilo of bodyweight daily in divided doses.

4.3 Contraindications

Use in patients hypersensitive to codeine, or hypersensitivity to any of the other constituents.

Use in patients with acute asthma, respiratory depression, acute alcoholism, head injuries, raised intra-cranial pressure and following biliary tract surgery.

Use in patients currently receiving or within 14 days of stopping monoamine oxidase inhibitory therapy. See also Section 4.6 Pregnancy and Lactation.

Use of codeine containing products is contraindicated in mothers who are breastfeeding unless prescribed by a doctor.

4.4 Special warnings and precautions for use

This product should only be used with great care in any patient whose condition may be exacerbated by opioids, particularly the elderly, who may be sensitive to its central and gastro-intestinal effects, those who are on concurrent CNS drugs, those with prostatic hypertrophy or those with inflammatory or obstructive bowel disorders.

Care should also be observed if prolonged therapy is contemplated.

Tolerance and dependence can occur, especially with prolonged high dosage of codeine.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms such as restlessness and irritability, once the drug is stopped.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Forms codeine phenobarbitone complex with phenobarbitone sodium and crystal of codeine periodide with potassium iodide.

The effects of CNS depressants (including alcohol) may be potentiated by codeine.

4.6 Pregnancy and lactation

Not recommended during pregnancy due to neonatal withdrawal symptoms and impaired effect on foetus.

In nursing mothers, who are ultra-rapid metabolisers of codeine, higher than expected serum and breast milk morphine levels can occur. Morphine toxicity in babies can cause excessive somnolence, hypotonia, miosis and difficulty breastfeeding or breathing. In severe cases respiratory depression and death can occur. In severe cases, naloxone may be appropriate to reverse the effects. The lowest effective dose should be used, for the shortest possible time.

Nursing mothers should be informed about carefully monitoring the infant during treatment for any signs and/or symptoms of morphine toxicity such as increased drowsiness or sedation, difficulty breastfeeding, breathing difficulties, miosis and decreased tone, and seeking immediate medical care if such symptoms or signs are noticed. The nursing mother should be informed about monitoring for signs and symptoms of maternal opioid toxicity as well. Should such signs/symptoms be noted in mother or baby, the mother should immediately stop taking all codeine-containing medicines and seek medical advice.

Codeine-containing products must not be used while breastfeeding unless prescribed by a doctor.

4.7 Effects on ability to drive and use machines

In combination with alcohol, Codeine Phosphate has a deleterious effect on driving.

Patients reviewing this medication should be advised not to drive or operate machinery if affected by dizziness or sedation.

4.8 Undesirable effects

Codeine can produce typical opioid effects including constipation, nausea, vomiting, dizziness, light-headedness, confusion, drowsiness and urinary retention. The frequency and severity are determined by dosage, duration of treatment and individual sensitivity.

4.9 Overdose

Nausea and vomiting are prominent symptoms of codeine toxicity and if there is evidence of circulatory and respiratory depression, suggested treatment is gastric lavage and catharsis. If CNS depression is severe, assisted ventilation, oxygen and parenteral naloxone may be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The action of codeine is largely that of Morphine from which it is derived i.e. it is a CNS depressant.

5.2 Pharmacokinetic properties

Codeine is metabolised in the liver and is excreted in the urine, largely in inactive forms. A small fraction (approximately 10%) of administered codeine is demethylated to form morphine; traces of free morphine can be found in the urine after therapeutic doses of codeine.

5.3 Preclinical safety data

Animal work suggested that the analgesic activity of Codeine was not affected by Acetylation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Magnesium Stearate
Sodium Starch Glycolate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

Opaque plastic securitainers 1000, 500, 250 and 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Ltd.
Spafield
Cork Road
Cashel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 408/42/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th February 1992

Date of last renewal: 24th February 2007

10 DATE OF REVISION OF THE TEXT

March 2008